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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

AUG 4 1991

MEMORANDUM

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

SUBJECT: OCCUPATIONAL AND RESIDENTIAL EXPOSURE ASSESSMENT AND
RECOMMENDATIONS FOR THE REREGISTRATION ELIGIBILITY
DOCUMENT FOR LINURON

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Please find the OREB review of

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This memorandum presents the OREB science chapter review for the Linuron Reregistration Eligibility Document (RED). Occupational and residential exposure data requirements to support the reregistration of Linuron are discussed in this chapter. Precautionary label language recommendations regarding personal protective equipment are also addressed.



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Occupational and Residential Exposure

Linuron is a substituted urea herbicide used to control germinating and newly emerging grasses and broad-leaved weeds. It is applied to agricultural crops, ornamental bulbs, and to poplar trees, for use in shelterbelts, in the mid-west. Formulations include water dispersable granules, wettable powders, flowable concentrates, and emulsifiable concentrates. Linuron is usually applied after the crop has been planted, but before the weeds emerge. In some cases, over-top sprays are applied to newly emerging crops such as carrots and celery. In asparagus, sprays may be applied between cuttings of newly emerging spears for weed control during harvesting activities. Current label directions allow for both ground and aerial applications. Although some registered uses are for crops that may be grown in home gardens, EPA is not aware of any products that are labelled primarily for home use.

Postapplication/reentry and mixer/loader/applicator exposure data are required when both toxicity and human exposure criteria are met. The application methods (broadcast and directed) result in direct exposure of mixer/loaders and applicators to the formulated product. When workers enter treated areas to perform hand labor tasks, such as thinning, cultivation, an harvesting, or to perform irrigation-related tasks, they may be exposed to residues on the soil surface and, following post-emergence applications and to residues on the foliage. Therefore, linuron meets the Agency's human exposure criteria. Guideline studies indicate that linuron is classified as Category III for acute oral and dermal toxicity, Category IV for acute inhalation toxicity, and Category III for primary eye and skin irritation. In the HED Toxicology Endpoint Selection document dated March 14, 1994, two endpoints were selected for assessing short-term and intermediate occupational exposure to linuron.

The endpoint for short-term, occupational exposure (1 to 7 days), is a NOEL of 12.1 mg/kg/day, based on maternal and developmental concerns. These concerns are based upon decreased maternal body weight and food consumption, increased post implantation loss, and increases in litter and fetal incidence of resorptions. The endpoint for intermediate-term occupational exposure (1 week to several months), is a NOEL of 1.25 mg/kg/day. This NOEL is based on reduced fertility at the LOEL of 6.25. A dermal absorption rate of 16% (for 8 to 10 hours exposure) was recommended for estimating the systemic dose (MRID 254943).

Mixer/Loader/Applicator Exposure (Handlers):

In the Guidance for the Reregistration of Linuron (June 29, 1984), the following personal protective equipment were required for mixer/loader/applicators handling linuron:

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One-piece overalls which have long sleeves and long pants constructed of finely woven fabric as specified in the USDA/WPA Guide for Commercial Applicators.

Wide-brimmed hat and heavy-duty fabric work gloves.

Instead of clothing and equipment specified above, the applicator can use an enclosed tractor cab which provides a filtered air supply (as described by Taschenberg and Bourke, 1975).

The PPE requirements were based on previous evidence indicating that linuron was a carcinogen, and, that lifetime exposures for mixer/loader/applicators resulted in an unacceptable risk, without those PPE. In a subsequent HED peer review committee and Science Advisory Panel, it was determined that the "carcinogenic potential of linuron in humans is weak, and it should not be regulated as a carcinogen (US EPA, 1989)".

Since the issuance of the Registration Standard in 1984, linuron product labels have been modified in response to PR Notice 93-7, which implemented the labelling requirements of the 1992 Worker Protection Standard for Agricultural Pesticides. These WPS-mandated label modifications established personal protective equipment (PPE) requirements on each end-use product depending on the acute toxicity of the end-use product. However, if the existing labelling contained PPE requirements more stringent than those that the WPS would establish, the more stringent requirements would be retained. Current linuron labels, therefore, may contain a variety of PPE requirements, depending on what other active ingredients and on what inert ingredients are included in a particular formulation, however, the minimum PPE on each end-use product containing linuron is "coveralls, chemical-resistant or waterproof gloves (sometimes), and chemical-resistant headgear for overhead exposure."

To reassess mixer/loader/applicator (handler) exposure to the newly identified adverse effects of linuron, data provided in the Pesticide Handlers Exposure Database (PHED) were used. In the assessment, exposure for ground-boom and aerial applicators was addressed as well as exposure for mixer/loaders using wettable powder and liquid formulations.

The data in PHED are normalized by pounds of active ingredient handled, and, are referred to as unit exposures. Whenever possible, surrogate unit exposures are chosen from studies having the same PPE as required on the labelling of the chemical currently being evaluated. When data are not available for certain clothing scenarios, existing data points are adjusted using a 50% protection factor based on the type of PPE (ie. a 50% reduction to hand exposure for the use of gloves). Although a 90% protection factor for gloves has been used by the OREB in the

past, a conservative 50% reduction was used in this assessment. The handler assessment presented in this memorandum assumes the use of long sleeved shirt, long pants, gloves, and coveralls. This double layer is an upgrade to existing PPE.

Applicator and mixer/loader exposure scenarios are presented in Appendix 1, attached to this memorandum. Information regarding the studies from which the surrogate data were selected, is provided in Appendix 2.

For all of the applicator scenarios, margins of exposure (MOE) are greater than 100. However, MOE's for certain mixer/loader scenarios are below 100 for both short-term and intermediate-term exposure. Particularly low, are those MOE's for mixer/loaders supporting the aerial applications. For those scenarios, MOE's are below 100 for intermediate-term exposure, even with the use of closed mixing/loading systems.

MOE's are also low for handlers using open mixing/loading for ground-boom applications. For this scenario OREB recommends closed mixing/loading systems be required.

Postapplication/Reentry Exposure (Workers):

The potential for postapplication/reentry exposure is unlikely following most applications of linuron. This is because most applications are made early in the season, before reentry tasks are likely, or, are made to crops that are mechanically harvested. The notable exception is asparagus where applications of linuron are made between asparagus cuttings. Current labelling indicates a 24-hour reentry interval, which was established in the 1984 Guidance Document. The 24-hour reentry interval established by the 1984 Guidance Document was converted into a 24-hour restricted-entry interval through modifications to the labelling specified in PR Notice 93-7, which implemented the labelling requirements of the 1992 Worker Protection Standard for Agricultural Pesticides.

To formally establish a REI, the registrant submitted a worker exposure study addressing asparagus worker exposure (MRID 403418-01). In the study, the registrant measured exposures for three worker tasks; harvesters, sledgers, and off-loaders. Harvesters cut the spears and leave them in bundles at various locations in the field. Sledgers drive a tractor and wagon along the field and pick up the bundles of asparagus left by the harvesters. Off-loaders unload the asparagus from the wagons at the packing house. Because asparagus harvesting occurs over a long period of time, the use of both the short-term (12.1 mg/kg/day) and the intermediate-term (1.25 mg/kg/day) end-points are appropriate for addressing postapplication/reentry exposure.

The study "Exposure of Asparagus Harvesters to Lorox® (Linuron) Herbicide in California, 1986" [MRID 403418-01] is considered supplemental, and can be used to evaluate the current use of linuron on asparagus. The sampling schedule was limited to 0 day, 1 day, and 3 days postapplication because of inclement weather. Therefore, a dissipation curve could not be established. However, off-loader exposure was measured on the first day of the study for workers handling asparagus treated 14 days prior to the initiation of the study. High winds and other complicating factors rendered the inhalation data unacceptable. OREB decided to use these supplemental data because the major route of exposure is via the dermal route. The task specific worker MOE's are presented in the following table:

MOE's for Asparagus Reentry Workers

TASK (DAT)	HOURLY EXPOSURE (mg/hour)	AVERAGE DAILY EXPOSURE (ADE) (mg/kg/day)	Short-Term (1 - 7 da) MOE	Intermediate (> 7 da) MOE
Harvest (1)	3.386	0.072	172	18
Sledder (1)	2.161	0.046	263	27
Off- Loader (1)	2.022	0.043	281	29
Harvest (3)	1.562	0.033	367	36
Sledder (3)	0.619	0.013	930	42
Off- Loader (3)	1.446	0.031	393	41
Off- Loader* (14)	0.6	0.013	945	98

DAT - Days After Treatment

* Exposed to asparagus treated at a rate of 1 lb ai/acre, 14 days before this exposure measurement.

ADE = $\frac{\text{hourly exposure} \times 8 \text{ hr}}{60 \text{ kg (body wt.)}} \times 16\%$

Restricted-Entry Interval (REI):

OREB recommends a restricted-entry interval (REI) of 14 days for all crops. The REI is based solely on the MOE's calculated for asparagus off-loaders handling spears from linuron sprayed fields 14 days after treatment. The data appear to indicate that exposure for asparagus workers is similar, regardless of task, although exposure measurements for harvesters were slightly higher. For crops that have little potential for early reentry exposure, the 14 day REI should not be overly burdensome. For crops such as celery and carrots, where intermediate exposure is likely, the 14 day REI is recommended until worker exposure data are submitted by the registrant and evaluated by the Agency.

The early-entry personal protective equipment requirements established for the products containing linuron are coveralls, chemical-resistant gloves, shoes, and socks.

Personal Protective Equipment (PPE) Requirements:

The personal protective equipment requirements for products containing linuron should, in general, be established based on the acute toxicity of the end-use product by route of entry as described in PR Notice 93-7 or other EPA guidance. However, due to the short-term and intermediate-term endpoints based on maternal and developmental concerns, OREB establishes minimum applicator personal protective equipment requirements for any end-use product containing linuron. Products containing linuron may contain more stringent PPE, but in no case may they require less stringent PPE than the following: coveralls over long-sleeved shirt and long pants, chemical-resistant gloves, chemical-resistant footwear plus socks, and chemical-resistant headgear for overhead exposure.

Closed-system mixing/loading is recommended for the ground-boom applications based on the low intermediated exposure MOE's for mixer/loader exposure. PPE similar to that required for the applicator must be available to the mixer/loader, in the event of a spill or leak.

Since the Agency is unaware of any linuron end-use products that are primarily intended for home-use, OREB will not establish entry restrictions or personal protective equipment requirements for those products at this time.

Data Requirements:

- | | |
|--------|---|
| 132-1a | Foliar Dislodgeable Residues (carrots and celery) |
| 132-1b | Soil Dislodgeable Residues (carrots and celery) |
| 133-3 | Dermal Exposure (carrots and celery) |
| 133-4 | Inhalation Exposure (carrots and celery) |

The Agency now requires that foliar and soil dislodgeable residue studies, and dermal and inhalation exposure studies be conducted concurrently.

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Appendix I. Summary Exposure Values for Linuron^a

Exposure Scenario	Application Type	Application Targets	Application Timing	Treatment Rate (lb ai/acre) ^b	Daily Maximum Treated (acres) ^c	Unit Dermal Exposure (mg/lb ai)	Unit Inhalation Exposure (mg/lb ai)	ADE ^d Combined Systemic Dose (mg/kg/day)	Short-term exposure MOE	Intermediate exposure MOE
Mixer Loader Exposure Levels										
Open Pour Liquids (I)	Aerial	Variable	Variable	1 - 2.5	350	0.113	0.00057	0.11 - 0.27	45 - 110	5 - 11
Open Mix Wettable Powder (II)	Aerial	Variable	Variable	1 - 2.5	350	0.2	0.0037	0.21 - 0.52	23 - 58	2 - 6
Open Pour Liquids (I)	Ground-boom	Variable	Variable	1 - 2.5	100	0.113	0.00057	0.03 - 0.08	157 - 403	16 - 42
Open Mix Wettable Powder (II)	Ground-boom	Variable	Variable	1 - 2.5	100	0.2	0.0037	0.06 - 0.15	81 - 205	8 - 21
Closed Mix (III)	Ground-boom	Variable	Variable	1 - 2.5	100	0.02	0.0003	0.006 - 0.015	> 500	86 - 214
Closed Mix (III)	Aerial	Variable	Variable	1 - 2.5	350	0.02	0.0003	0.02 - 0.05	> 200	25 - 63
Applicator Exposure Levels										
Ground-boom Application (IV)	Broadcast	Asparagus, Direct Seeded or newly planted crowns	Preemergence	1 - 2 Two lb ai per season	50	0.014	0.0004	0.002 - 0.004	> 1000	> 300
Ground-boom	Broadcast	Asparagus, Direct Seeded or newly planted crowns	Postemergence	0.5 - 1 One to two applications per season	50	0.014	0.0004	0.001 - 0.002	> 1000	> 500
Ground-boom	Broadcast	Asparagus, Established Beds	Preemergence	1 - 2 One application	50	0.014	0.0004	0.002 - 0.004	> 1000	> 300
Ground-boom	Broadcast	Asparagus, Established Beds	Postemergence, before cutting season or immediately after cutting	0.5 - 1 One to four applications	50	0.014	0.0004	0.001 - 0.002	> 1000	> 500

Table 1. (Continued)

Exposure Scenario	Application Type	Application Targets	Application Timing	Treatment Rate (lb ai/acre) ^a	Daily Maximum Treated (acres) ^c	Unit Dermal Exposure (mg/lb ai)	Unit Inhalation Exposure (mg/lb ai)	ADE ^b Combined Systemic Dose (mg/kg/day)	Short-term exposure MOE	Intermediate exposure MOE
Ground-hoorn	Broadcast	Asparagus, Established Beds (fern stage)	Directed Postemergence	2 - 4 One application	50	0.014	0.0004	0.004 - 0.004	> 1000	> 100
Ground-hoorn	Broadcast	Bulbs, (calla lily, daffodil, tulip, Dutch iris)	After Planting, before plants emerge	1 One application	25	0.014	0.0004	0.001	> 1000	> 1000
Ground-hoorn	Broadcast	Carrots, Florida	Preemergence	0.5 - 1 No more than 2 lb ai per season	100	0.014	0.0004	0.002 - 0.004	> 1000	> 250
Ground-hoorn	Broadcast	Carrots, Ohio Michigan, and Wisconsin	Preemergence	0.5 - 1.5 No more than 2 lb ai per season	60	0.014	0.0004	0.001 - 0.004	> 1000	> 250
Ground-hoorn	Broadcast	Carrots, East of the Rocky Mountains	Postemergence, Non-directed spray after carrots are 3" tall	0.75 - 1.5 A repeat application may be made. No more than 2 lb ai/crop	15	0.014	0.0004	0.001	> 1000	> 1000
Ground-hoorn	Broadcast	Celery, East of the Rocky Mountains	Non-Directed Spray After Transplanting	0.75 - 1.5 One application	100	0.014	0.0004	0.003 - 0.007	> 1000	> 150
Ground-hoorn	Broadcast	Corn, East of the Rocky Mountains	Preemergence, after planting	0.375 - 1.5 One application	100	0.014	0.0004	0.002 - 0.007	> 1000	> 150
Ground-hoorn	Broadcast	Corn (Field and Sweet)	Postemergence, directed spray after corn is at least 15" high	0.625 - 1.5 One application	100	0.014	0.0004	0.003 - 0.007	> 1000	> 150

Table 1. (Continued)

Exposure Scenario	Application Type	Application Targets	Application Timing	Treatment Rate (lb ai/acre) ^a	Daily Maximum Treated (acres) ^c	Unit Dermal Exposure (mg/lb ai)	Unit Inhalation Exposure (mg/lb ai)	ADE ^b Combined Systemic Dose (mg/kg/day)	Short-term exposure MOE	Intermediate exposure MOE
									1 to 7 days	7 days to several months
Ground-boom	Broadcast	Parsley, Texas	Preemergence, after planting	1.5 One application	2.5	0.014	0.0004	0.002	> 1000	> 700
Ground-boom	Broadcast	Parsnips	Preemergence, after planting	0.75 - 1.5 One application	1.5	0.014	0.0004	0.001	> 1000	> 1000
Ground-boom	Broadcast	Poplar (Shelterbelt), Midwest	Directed spray after bud break in the spring	1 - 2 No more than 4 lb ai/year	2.5	0.014	0.0004	0.001 - 0.002	> 1000	> 600
Ground-boom	Broadcast	Potatoes, East of the Rocky Mountains	Preemergence, after planting	0.75 - 2 One application	100	0.014	0.0004	0.003 - 0.007	> 1000	> 150
Ground-boom	Broadcast	Potatoes, Wisconsin (Central Sands Area)	Preemergence, after planting	0.5 - 1 One application	100	0.014	0.0004	0.002 - 0.004	> 1000	> 250
Ground-boom	Broadcast	Sorghum	Preemergence	0.313 - 1 One application	100	0.014	0.0004	0.001 - 0.004	> 1000	> 300
Ground-boom	Broadcast	Sorghum	Postemergence, Directed spray	0.5 - 1 One application	100	0.014	0.0004	0.002 - 0.004	> 1000	> 250
Ground-boom	Broadcast	Soybeans, Conventional Tillage	Preemergence	0.16 - 2.5 One application	100	0.014	0.0004	0.001 - 0.01	> 1000	> 100
Ground-boom	Broadcast	Soybeans, Minimum or No-Tillage	Preemergence	0.375 - 2.5 One application	100	0.014	0.0004	0.001 - 0.01	> 1000	> 100

ble 1. (Continued)

Exposure Scenario	Application Type	Application Targets	Application Timing	Treatment Rate (lb ai/acre) ^a	Daily Maximum Treated (acres) ^c	Unit Dermal Exposure (mg/lb ai)	Unit Inhalation Exposure (mg/lb ai)	ADE ^b Combined Systemic Dose (mg/kg/day)	Short-term exposure MOE	Intermediate exposure MOE
Ground-hoorn	Broadcast	Soybeans	Postemergence. Directed spray	0.5 - 1 Up to two applications not to exceed 1 lb ai	100	0.014	0.0004	0.002 - 0.004	> 1000	7 days to several months
Aerial (total deposition) (V)	Broadcast	Variable	Variable (not including directed sprays)	1 - 2.5	350	0.004	0.0002	0.005 - 0.01	> 1000	> 100

Liquid and wettable powder linuron formulations were chosen to represent best and worst case scenarios respectively.

A range of application rates are provided whenever the amount used is based on soil types, cropping systems, tank mixes, or weed species.

Daily maximum treated acres are based either on the amount acreage that can be treated in one day or based on average farm size. The average farm size is based on data presented in the 1987 Census of Agriculture. These values should be validated/refined by BEAD if the exposure assessment needs to be refined.

The Average Daily Exposure (ADE) (mg/kg/day) = [(Exposure (mg/lb ai) * Appl. Rate (lb ai/acre) * Acres Treated)/60 kg]. A 16% dermal absorption rate was assumed for dermal exposure and 100% absorption was assumed for inhalation exposure. Values presented in this column were rounded to the second decimal place for mixer/loaders and to the third decimal place for applicators. The Margins of Exposure (MOE) were calculated using the unrounded values.

Appendix 2. Exposure Scenario Descriptions for Linuron*

Exposure Scenario (Scene #)	Data Source	Clothing Scenario	Equipment	Formulations	Standard Assumptions (8-hour work day)	Comments
Mixer/Loader Exposure Levels						
Open Pour Liquids (I)	PHED	Long Pants, Long-Sleeves, No Gloves	Open System	All Liquids	For all liquid formulations plus dry flowables such as water dispersible granulars	Acceptable PHED grades, 14+ replicates, 50% protection factor applied to hand exposure to account for the use of chemical resistant gloves.
Open Mix Wettable Powders (II)	PHED	Total Deposition	Open System	PHED Wettable Powder Category	Wettable powder only	All PHED grades, 3 to 14 replicates, 50% protection factor applied to dermal and to hand exposure levels to account for the use of normal work clothing and chemical resistant gloves.
Closed Mix Liquids (III)	PHED	Total Deposition	Closed System	PHED Closed System Category	All closed systems considered similar for this assessment	PHED grades A/B/C, 13 replicates, 50% protection factor applied to dermal and to hand exposure levels to account for the use of normal work clothing and chemical resistant gloves.
Applicator Exposure Levels						
Ground-boom Application (IV)	PHED	Long Pants, Long-Sleeves, No Gloves	PHED Ground-boom Category/Open Cab	All Formulations	Tractor based ground-boom	PHED grades A/B/C, 6+ replicates, 50% protection factor applied to hand exposure to account for the use of chemical resistant gloves, and for the use of coveralls.
Aerial (V)	PHED	Long Pants, Long-Sleeves, No Gloves	PHED Aerial Fixed Wing Category	All Formulations	All fixed-wing aerial data	No helicopter data available. all PHED grades, 4 to 41 replicates, 50% protection factor applied to hand exposure to account for the use of chemical resistant gloves when entering and exiting aircraft.

* All exposure levels presented in Appendix 1 reflect the current PPE requirements for linuron handlers. Any exposure values which did not reflect the required clothing scenario were adjusted using protection factors (see comments). Unit dermal exposure was assumed to be 50 percent hand exposure and 50 percent remaining dermal exposure. All dermal exposure values are the "best" fit mean. The "best" fit mean is the composite total dermal exposure based on using the geometric mean for lognormal distributed data, arithmetic mean for normal distributed data, and the median for all other distribution types.